IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al., ex rel. DONALD R. GALMINES,	:	
	:	Civil Action No. 06-3213
BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, and TENNESSEE, THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, and THE DISTRICT OF COLUMBIA,	:	
Plaintiffs and Relator,	:	
v.	:	Judge Gene E.K. Pratter
NOVARTIS PHARMACEUTICALS CORP.,	:	
Defendant.	:	

RELATOR'S MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS THE AMENDED COMPLAINT

I. Introduction

On October 25, 2012, the Court dismissed Mr. Galmines's Complaint without prejudice on the sole ground that "Relator has failed to sufficiently allege that he voluntarily provided information to the government before filing this action." Doc. 58. The Court provided the opportunity to file an Amended Complaint to cure this defect. Relator filed an Amended Complaint (Doc. 61-1) on December 3, 2012 which added only allegations relating to the pleading issue identified by the Court in its Order, *i.e.*, showing that he voluntarily provided information to the government before filing this action. In support of this allegation, which is part of the jurisdictional inquiry into the original-source status of a *qui tam* relator under that version of the

False Claims Act which was in effect when the Complaint was filed, Mr. Galmines provided the dates and times of a number of oral and written communications with representatives of the United States and *qui tam* states. Defendant's new motion to dismiss contests none of this, and so concedes that the Amended Complaint satisfies the jurisdictional requirement identified by the Court.

Defendant has nonetheless renewed its Motion to Dismiss, incorporating its previous briefs and adding several new pages. Relator incorporates his previous briefs (Docs. 45 and 56) as well as oral argument held on October 26, 2011 (Doc. 55), and hereby responds as briefly as possible to the Defendant's new material. For the reasons set forth below and in his previous briefs, the motion before the Court should be denied and Mr. Galmines should be permitted to proceed with his case.

II. Argument

Relator Galmines and Defendant Novartis appear to have substantially different views of the Court's dismissal entry. Relator understood the Court's direction to permit amendment as to the single issue that Order addressed: Allegations relating to the prefiling disclosure of Relator's allegations to the United States. Novartis appears to believe that by not adding to the resulting Amended Complaint allegations to address Novartis's Rule 9(b) and other claims in its original motion to dismiss, Relator has tacitly conceded that he cannot do so.

This assertion reads far too much into the Court's Order. Relator reiterates that, should the Court wish additional detail regarding these claims, it can be provided; examples of many such facts are set out in earlier briefing (Doc. 56 at 6-7). Relator further notes that Novartis's argument that the Amended Complaint does not provide it with sufficient basis to defend in this

case is uniquely odd: Novartis understands those allegations well enough that, the same week as the Court's entry, Novartis paid the State of Texas $20 million on account of Mr. Galmines's allegations;[1] the settlement agreement in that case is attached hereto as Exhibit 1.

But if the Court believes that additional detail is needed, Relator respectfully renews his request that the Court indicate the areas of its concern so that Relator can address them in an amendment which is not targeted to a specific jurisdictional concern.

A. This case is not barred by the First-to-File Provision

31 U.S.C. § 3730(b)(5) bars a "related action based on the facts underlying the pending action." The policy reasons behind the first-to-file provision are stated in *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.,* 149 F.3d 227, 232-33 (3rd Cir. 1998). As *LaCorte* noted, "duplicative claims do not help reduce fraud or return funds to the federal fisc,

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[1] The Texas Attorney General's October 30, 2012 press release, available online at https://www.oag.state.tx.us/oagnews/release.php?id=4206, states:

> Under today's agreement, Novartis must pay a total of $19.9 million to resolve the State of Texas and the federal government's allegations of off-label marketing. Texas' share of the settlement proceeds is $6,638,250. The State's investigation revealed that Novartis unlawfully marketed eczema drug Elidel to treat infant children while failing to disclose the drug's known harmful side effects – including cancer-related risks. Evidence uncovered by the State revealed that Novartis improperly urged physicians to prescribe Elidel to children under two years of age for purposes that had not been approved by the U.S. Food and Drug Administration. Because of the defendant's misrepresentations, the Texas Medicaid program overpaid for Elidel prescriptions.
>
> Because Medicaid is jointly funded by the State and the federal government, the federal government is entitled to a share of the $19.9 million total monetary settlement. Under the Texas Medicaid Fraud Prevention Act, the relator-whistle-blower who uncovered the defendant's unlawful conduct and reported it to authorities will also receive a share of the total monetary settlement. Additionally, the Texas Attorney General's Office and the relator-whistleblower will recover investigative and legal costs associated with the enforcement action.

since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *Id.* at 234. Recent cases cited by Defendant do not differ from the policy behind this provision.[2]

Defendant continues to assert that the complaint in *United States ex rel. Moyer and Shelton v. Novartis Pharmaceutical Corp.,* No. 05-72242 (E.D. Mich., complaint filed June 7, 2005), bars Mr. Galmines's case because it was the first-filed complaint raising the same allegations as the Complaint here. This argument is simply incorrect. The Third Circuit holds that "if a later allegation states **all the essential facts** of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim even if that claim incorporates somewhat different details." *Id*. at 232-33 (*emphasis supplied*). *Moyer* did not put the government on notice to "all the essential facts" of the fraudulent scheme identified by Mr. Galmines.

No reader of the *Moyer* complaint could possibly know that Novartis was marketing Elidel and offering kickbacks to physicians who used it on infants and for first-line or chronic use. These allegations by Mr. Galmines are more than simply "details" which augment *Moyer*. Rather, Mr. Galmines identifies the essential facts of a fraudulent scheme never identified by *Moyer*, and which the government never had knowledge to investigate. Moreover, Mr. Galmines' allegations put the government on notice of *new* claims, not duplicative—the patient populations

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[2] *United States ex rel. Banignan v. Organon U.S.A. Inc.,* 2012 U.S. Dist. LEXIS 76130, *35 (D. Mass. June 1, 2012) ("While the FCA's first-to-file bar precludes a qui tam suit where a prior action gave the government sufficient notice of the essential elements of fraud, the policy underlying the provision counsels that **the bar should not apply if the government would uncover such fraud (if at all) only by exhausting its investigative resources**") (emphasis added); *United States ex rel. Heineman-Guta v. Guidant Corp.*,874 F. Supp. 2d 35, fn12 (D. Mass. 2012) ("The court can imagine … the possibility of a first-filed complaint that is so spurious or vacuous as to provide no real notice of fraud to the government, and **therefore not serve to bar later-filed complaints of genuine substance**") (*emphasis added*).

targeted by Novartis' off-label marketing and kickback campaign in the present action are different than the target patient population alleged in *Moyer*. To allow *Moyer* to bar the factually distinct allegations by Mr. Galmines would unnecessarily and inappropriately impede the very fundament of the False Claims Act: Incentivizing and rewarding those who are *actually knowledgeable* of a defendant's fraud.[3]

B. Relator is an original source of his allegations.

Defendant no longer argues the sole basis for the Court's order granting, in part, the original motion to dismiss: That Relator voluntarily provided information to the government before filing his action, one of the required prerequisites to establishing that Mr. Galmines is an original source. 31 U.S.C. 3730(e)(4)(B). Instead, Defendant relies on one discredited decision from the Sixth Circuit, asking this Court to hold that in order to be an original source, a whistleblower must disclose allegations to the government *before the public disclosure*. As noted in Relator's earlier papers, this position has been rejected by several courts and should not be adopted by this Court. Indeed, as Novartis concedes, one of the two courts which accepted this implausible argument has now reversed itself. In *United States ex rel. Davis v. District of Columbia,* 679 F.3d 832, 838-39 (D.C. Cir. 2012), the court reversed *U.S. ex rel. Settlemire v. Dist. of Columbia*, 198 F.3d 913,915-16 (D.C. Cir. 1999), and joined the vast majority of courts which hold that the voluntary disclosure must happen before the filing of the complaint—not

[3] Pursuant to those same considerations, the Ninth and Sixth Circuits have permitted subsequent complaints to survive a first-to-file challenge when the first action was dismissed as "jurisdictionally defective because the relator was not an original source of publicly disclosed information." *Campbell v. Redding Med. Center*, 421 F.3d 817, 818 (9th Cir. 2005). "Congress sought to provide incentives to qui tam whistleblowers to come forward, and we believe that an overly broad interpretation of the first-to-file bar, allowing even sham complaints to preclude subsequent meritorious complaints in a public disclosure case, would contravene this intention." *Id* at 821; *accord, Poteet v. Medtronic, Inc.,* 552 F.3d 503 (6th Cir. 2009) (*citing Campbell*).

before the public disclosure. *Accord, e.g.*, *United States ex rel. Merena v. SmithKlineBeecham*, 114 F. Supp. 2d 353, 359-60 (E.D. Pa. 2000); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 22 (1st Cir. 2009); *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1351 (4th Cir. 1994).

As noted in Relator's earlier filings, the Complaint is replete with facts showing Mr. Galmines had both direct and independent knowledge of the information upon which his case is based. It describes the improper training he received to promote Elidel for off-label uses, including that it "must be safe" for infant use (Doc. 61-1, ¶¶ 56-59, 65, 67-69, 71, 77-83, 91-93, 95, 98). He includes information that this message was detailed to physicians (*e.g., id.* at ¶ 80) and that sales representatives from all U.S. regions were trained on how to market off-label and to assert that Elidel was safe for infants (*e.g., id.* at ¶¶ 86-88, 95). He also described that the most successful representatives were those that *sold* off-label (*id.* at ¶ 87) and that 20% of prescriptions of Elidel were written off-label to children under two years of age (*id.* at ¶ 116). He also provided information to show Novartis' knowledge of the prescription-writing habits of physicians and its direct instruction to detail to these doctors off-label indications. (*Id.* at ¶ 97). Additionally, Mr. Galmines' allegations of Novartis's improper kickback schemes are *entirely* from his direct and independent knowledge, (¶¶ 117-143), and included knowledge not only of Novartis' purpose to induce (*e.g.*, ¶¶ 117, 132) but also of specific doctors who committed to prescribe Elidel as a result (*e.g.*, ¶¶ 119, 141). Mr. Galmines had both direct and independent knowledge of the information upon which his case is based.

C. The Amended Complaint sets out claims upon which relief may be granted.

Relator alleges that each government-funded health program identified in the Amended Complaint does not reimburse for off-label uses (*i.e.* not prescribed for a medically-accepted indication) nor for drugs the prescribing of which was influenced by unlawful inducements. Amended Complaint, Doc. 61-1, at ¶ 24. To very briefly recap: Relator alleges that, as the Texas press release states, "Novartis unlawfully marketed eczema drug Elidel to treat infant children while failing to disclose the drug's known harmful side effects – including cancer-related risks." In fact, even after the FDA put a "Black Box" around Elidel, Novartis *continued* to bribe doctors to tell parents to use it on their babies. Doc. 61-1 at ¶ 125.

As detailed in Relator's prior filings (Doc.45 at 30-56), these allegations state claims under the False Claims Act. While Novartis contends that Relator did not allege that government healthcare programs must deny payment of off-label claims for Elidel, this is simply not so. (*Compare* Doc. 62 at 10 with Doc. 61-1 at ¶¶ 24, 146-149).

Finally, the Defendant argues that a recent non-False Claims Act case, in which a pharmaceutical representative was criminally prosecuted for *truthful* off-label statements, demonstrates that Relator has failed to state a claim against it for lying to physicians about the safety and efficacy of slathering Elidel on infants. Doc. 62 at 9, *citing United States v. Caronia*, 2012 U.S. App. LEXIS 24831 (2d Cir. Dec. 3, 2012). *Caronia* is wildly inapposite to the facts here.[4] Relator alleges that Novartis engaged in repeated, *false* statements in marketing Elidel for

[4] In addition to the fact that *Caronia* is not controlling law and involves a criminal prosecution in which truthful statements were made, the court's opinion centered on the fact that the prosecution of conspiracy to introduce a misbranded drug into interstate commerce reflected a focus on the off-label promotion rather than promotion as *evidence* of the intended use of the drug in question. *Id.* at *24.

off-label use and bribed physicians to yield to its fraudulent marketing efforts–in violation of the FCA.

D. Should the Court deem the Complaint insufficient, any dismissal should be without prejudice.

Mr. Galmines's prior filings identify a variety of additional allegations which can be made in support of his complaint, should the Court view such further amendment necessary. As stated at oral argument (Transcript, at 56-57) and in previous briefs, Relator can provide further detail if necessary. Relator submits that no further amendment is necessary; but if the Court disagrees, such an amendment patently would not be futile.

III. Conclusion

For the reasons stated above and in Relator's prior memoranda (Docs. 45 and 56) no portion of the Complaint in this case should be dismissed. If any part of it is, Relator respectfully requests that dismissal is without prejudice.

Dated: January 14, 2013

Respectfully submitted,

/s/ Frederick M. Morgan, Jr.
Frederick M. Morgan, Jr., *pro hac vice*
Jennifer M. Verkamp
Morgan Verkamp, LLC
700 Walnut Street, Suite 400
Cincinnati, Ohio 45202
Phone (513) 651-4400
Fax (513) 651-4405
Rick.morgan@morganverkamp.com

/s/ Marc P. Weingarten
Marc P. Weingarten
Locks Law Firm
601 Walnut Street
Philadelphia, PA 19106
(215) 893-0100

Attorneys for Mr. Galmines

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UNITED STATES OF AMERICA, et al., ex rel. DONALD R. GALMINES, BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, HAWAII, ILLIONOIS, INDIANIA, LOUISIANA, MICHIGAN, NEVADA, AND TENNESSEE, THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, AND THE DISTRICT OF COLUMBIA, Plaintiffs and Relator, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	:	Civil Action No. 06-3213 Judge Gene E.K. Pratter

ORDER DENYING DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO DISMISS

AND NOW, this ___ day of ___, 2013, upon consideration of Defendant Novartis Pharmaceuticals Corporation's Motion to Dismiss Relator's First Amended Complaint, and all briefs submitted by both parties, it is ORDERED that the Motion to Dismiss is DENIED in its entirety.

BY THE COURT:

_____
HON. GENE E.K. PRATTER
United States District Judge

CERTIFICATE OF SERVICE

I certify that on January 14, 2013, all counsel who are registered with the Court's Electronic Case Filing System with respect to this matter were served a copy of this memorandum through that system. Additionally, I served, by electronic mail transmission a copy of this memorandum, to the following attorneys:

Gregory B. David, Esq.
Assistant U.S. Attorney
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106

Elizabeth Valentine, Esq.
Assistant Attorney General,
Health Care Fraud
State of Michigan
Office of the Attorney General
2860 Eyde Parkway
East Lansing, MI 48823

/s/ Frederick M. Morgan, Jr.
Frederick M. Morgan, Jr.